Reference number(s)
2635-A

SPECIALTY GUIDELINE MANAGEMENT

TIBSOVO (ivosidenib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. Newly-Diagnosed Acute Myeloid Leukemia
   Tibsovo is indicated for the treatment of newly-diagnosed acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test in adult patients who are ≥ 75 years old or who have comorbidities that preclude use of intensive induction chemotherapy.

2. Relapsed or Refractory Acute Myeloid Leukemia
   Tibsovo is indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.

B. Compendial Uses

1. As a single agent in patients 60 years of age or older with IDH1-mutated AML in the following settings:
   a. Treatment induction when not a candidate for intensive remission induction therapy or declines intensive therapy OR
   b. Post-remission therapy following response to previous lower intensity therapy with the same regimen
2. Subsequent treatment as a single agent for progression on or after systemic treatment for unresectable or metastatic cholangiocarcinoma with an IDH1 mutation

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review (new starts only): medical record documentation of isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test

III. CRITERIA FOR INITIAL APPROVAL

A. Acute Myeloid Leukemia (AML)

1. Authorization of 12 months may be granted for treatment of newly diagnosed AML with a susceptible IDH1 mutation as a single-agent when any of the following criteria is met:
   i. Member is 75 years of age or older

ii. Member has comorbidities that preclude the use of intensive induction chemotherapy
iii. Member is 60 years of age or older and declines intensive induction chemotherapy

2. Authorization of 12 months may be granted for post-remission therapy for AML with a susceptible IDH1 mutation when all of the following criteria is met:
   i. The requested medication will be used as a single-agent
   ii. Member is 60 years of age or older
   iii. Member has experienced response to previous lower intensive therapy with the same requested regimen

3. Authorization of 12 months may be granted for treatment of relapsed or refractory AML with a susceptible IDH1 mutation.

B. Cholangiocarcinoma
Authorization of 12 months may be granted for subsequent treatment of unresectable or metastatic cholangiocarcinoma as a single agent in members with an IDH-1 mutation.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III who have not experienced an unacceptable toxicity.

V. REFERENCES

1. Tibsovo [package insert]. Cambridge, MA: Agios Pharmaceuticals, Inc; May 2019.
2. The NCCN Drugs & Biologics Compendium 2020 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed June 3, 2020.